

1                   10.     (Amended) [The] A method of [claim 1,] visually quantifying an  
2 amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair  
3 (sbp member), comprising:  
4                   providing a lateral flow matrix which defines a flow path and which comprises  
5 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture  
6 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that  
7 is complementary to or analogous to the analyte, and each of the one or more capture zones  
8 comprises at least a second sbp member immobilized in the capture zone, the second sbp  
9 member being complementary to the analyte;  
10                  contacting the sample with the sample receiving zone, whereby the sample  
11 flows along the flow path;  
12                  observing a pattern of label that accumulates at the one or more capture zones;  
13 and  
14                  correlating a pattern of label accumulated in the one or more capture zones to  
15 the amount of analyte in the sample;  
16                  wherein the second sbp member is an antibody against a complex formed  
17 between the analyte and the first sbp member.

1                   15.     (Amended) [The] A method of [claim 1,] visually quantifying an  
2 amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair  
3 (sbp member), comprising:  
4                   providing a lateral flow matrix which defines a flow path and which comprises  
5 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture  
6 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that  
7 is complementary to or analogous to the analyte, and each of the one or more capture zones  
8 comprises at least a second sbp member immobilized in the capture zone, the second sbp  
9 member being complementary to the analyte;  
10                  contacting the sample with the sample receiving zone, whereby the sample  
11 flows along the flow path;  
12                  observing a pattern of label that accumulates at the one or more capture zones;  
13 and

14 correlating a pattern of label accumulated in the one or more capture zones to  
15 the amount of analyte in the sample;

16 wherein the sample receiving zone comprises an amount of a third sbp member  
17 immobilized within the sample receiving zone and complementary to the analyte, the amount  
18 being sufficient to bind a threshold level of the analyte.

1 23. (Amended) [The] A method of [claim 18,] determining an amount of  
2 an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp  
3 member), comprising:

4 providing a lateral flow matrix which defines a flow path and which comprises  
5 in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture  
6 zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that  
7 is complementary to the analyte, and each of the one or more capture zones comprises at least a  
8 second sbp member immobilized in the capture zone, the second sbp member being analogous  
9 to the analyte;

10 contacting the sample with the sample receiving zone, whereby the sample  
11 flows along the flow path;

12 observing a pattern of labeled first sbp member that accumulates at the one or  
13 more capture zones; and

14 correlating a pattern of label accumulated in the one or more capture zones to  
15 the amount of analyte in the sample;

16 wherein the labeled first sbp member includes a visually detectable label;

17 wherein the sample receiving zone comprises an amount of a third sbp member  
18 immobilized within the sample receiving zone and complementary to the analyte, the amount  
19 being sufficient to bind a threshold level of the analyte.

1 In claim 53, lines 9-10, after the words "complementary to", delete the words  
2 "or analogous to".

1 In claims 56-57, change the claim dependencies from "claim 55" to --  
2 claim 53--.

1 In claim 58, change the dependency from "claim 59" to --claim 57--.

1 In claims 59-61, change the dependencies from "claim 55" to --claim 53--.

1 62. (Amended) [The] A device [of claim 55,] for determining an amount of  
2 an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp  
3 member), comprising a lateral flow matrix which defines a flow path and which comprises in  
4 series:

5 a sample receiving zone;

6 a labeling zone; and

7 one or more serially oriented capture zones;

8 wherein the labeling zone comprises a diffusively bound labeled first sbp  
9 member that is complementary to or analogous to the analyte, and each of the one or more  
10 capture zones comprises at least a second sbp member immobilized in the capture zone, the  
11 second sbp member being complementary to the analyte;  
12 wherein the second sbp member is an antibody against a complex formed between the analyte  
13 and the first sbp member.

1 In claim 63, change the dependencies from "claim 55" to --claim 53--.

1 In claim 65, change the dependency from "claim 55" to --claim 53--.

1 In claim 66, change the dependency from "claim 67" to --claim 65--.

1 In claims 67-68 and 70, change the claim dependencies from "claim 55" to --  
2 claim 53--.

1 69. (Amended) [The] A device [of claim 55,] for determining an amount of  
2 an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp  
3 member), comprising a lateral flow matrix which defines a flow path and which comprises in  
4 series:

5 a sample receiving zone;

6 a labeling zone; and

7                   one or more serially oriented capture zones;  
8                   wherein the labeling zone comprises a diffusively bound labeled first sbp  
9                   member that is complementary to the analyte, and each of the one or more  
10                  capture zones comprises at least a second sbp member immobilized in the capture zone, the  
11                  second sbp member being complementary to the analyte;  
12                  wherein the sample receiving zone comprises an amount of a third sbp member immobilized  
13                  within the sample receiving zone and complementary to the analyte, the amount being  
14                  sufficient to bind a threshold level of the analyte.

1                   In claim 71, change the dependency from "claim 72" to --claim 70--.

1                   In claims 73 and 74, change the claim dependencies from "claim 74" to --claim  
2                  72--.

1                   In claim 75, change the claim dependency from "claim 76" to --claim 74--.

1                   In claims 76-78, and 80, change the claim dependencies from "claim 74" to --  
2                  claim 72--.

1                   79.     (Amended) [The] A device [of claim 74,] for determining an amount of  
2                   an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp  
3                   member), the device comprising a lateral flow matrix which defines a flow path and which  
4                   comprises in series:

5                   a sample receiving zone;

6                   a labeling zone; and

7                   one or more serially oriented capture zones;

8                   wherein the labeling zone comprises a diffusively bound labeled first sbp member that is  
9                   complementary to the analyte, and each of the one or more capture zones comprises at least a  
10                  second sbp member immobilized in the capture zone, the second sbp member being analogous  
11                  to the analyte;

12 wherein the sample receiving zone comprises an amount of a third sbp member immobilized  
13 within the sample receiving zone and complementary to the analyte, the amount being  
14 sufficient to bind a threshold level of the analyte.

In claim 81, change the claim dependency from "claim 82" to --claim 80--.

120. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of any one of claims [55,] 53 or 74[, **84, 98 or 110**], a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

Please add new claims 121-143 as follows:

--121 (New). The device of claim 53, wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.--

122 (New). The device of claim 121 wherein the ligand is a hapten and the receptor is a complement to the hapten.

123 (New). A method of visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones;  
and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein said first sbp member includes a visually detectable particulate or nonparticulate label, said particulate label comprising dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

124. (New) The method of claim 123, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

125. (New) The method of claim 123, wherein the second spb member is a ligand capable of binding the analyte.

126. (New) The method of claim 123, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

127. (New) The method of claim 123, wherein the analyte is a polyepitopic molecule and the first and second sbp members are antibodies against different epitopes of the analyte.

128. (New) The method of claim 126, wherein the ligand is a hapten and the receptor is a complement to the hapten.

129. (New) The method of claim 123, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones, and the step of observing a pattern of label that accumulates at the one or more capture zones comprises determining a number of capture zones at which label accumulates.

130. (New) The method of claim 123, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the

single capture zone and the step of observing a pattern of labeled first sbp member that accumulates at the one or more capture zones comprises observing a distance traversed by the label along the single capture zone.

131. (New). A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein said first sbp member includes a visually detectable particulate or nonparticulate label, said particulate label comprising dyed latex beads, erythrocytes, liposomes, dyes sols, metallic colloids, or stained microorganisms.

132. (New) The device of claim 131, wherein the second sbp member is attached to particles and the particles are immobilized in the capture zones.

133. (New) The device of claim 131, wherein the second sbp member is an antibody capable of binding the analyte.

134. (New) The device of claim 131, wherein the second sbp member is labelled with a ligand and is immobilized on the capture zone by a receptor for the ligand coimmobilized on the capture zone.

135. (New). The device of claim 131, wherein the second sbp member is an antibody capable of binding the analyte.

136. (New) The device of claim 131 wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.

137. (New) The device of claim 138 wherein the ligand is a hapten and the receptor is a complement to the hapten.

138. (New) The device of claim 131, wherein the analyte is human IgE.

139. (New) The device of claim 131, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

140. (New) The device of claim 131, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

141. (New) The device of claim 131, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

142. (New) The device of claim 131, wherein the device comprises a plurality of discrete lateral flow matrices.

143. (New) The device of claim 142, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.--